

## PATENT COOPERATION TREATY

REC'D 15 MAR 2005

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 614067C:RDC	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).	
International Application No. <b>PCT/AU2003/001450</b>	International Filing Date (day/month/year) 4 November 2003	Priority Date (day/month/year) 15 November 2002
International Patent Classification (IPC) or national classification and IPC <b>Int. Cl. <sup>7</sup> A61M 1/10, 1/12</b>		
Applicant <b>SUNSHINE HEART COMPANY PTY LTD et al</b>		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 27 May 2004	Date of completion of the report 2 March 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  <b>SWAYAM CHINTAMANI</b> Telephone No. (02) 6283 2202

**I. Basis of the report**

1. With regard to the elements of the international application:\*
- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,  
pages , as amended (together with any statement) under Article 19,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of
2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
These elements were available or furnished to this Authority in the following language which is:
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
4. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.
5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*
- \* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).
- \*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims 1-57	YES
	Claims	NO
Inventive step (IS)	Claims 1-57	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-57	YES
	Claims	NO

**2. Citations and explanations (Rule 70.7)**

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1 US 5453076 A  
D2 WO 2000/012168 A1  
D3 EP 0363203 A2

**Novelty (N) Claims 1-57**

Claims 1-57 meet the criteria set forth in PCT Article 33(2) for novelty. The prior art published before the priority date does not disclose an intraluminal inflatable counter-pulsation balloon or chamber and a means to hold the balloon against a wall of the vessel.

**Inventive Step (IS) Claims 1-57**

The claimed invention is not obvious in the light of any of the cited documents nor is it disclosed in any obvious combination of them. It is also considered that it would not be obvious to a person skilled in the art in the light of common general knowledge either by itself or in combination with any of these documents.

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claim 7 is not clear because the term "the frame is balloon" is not clear.
2. The scope of several claims is in general not clear because they define features related to how the device is used or how the device is implanted. For example see claims 18 and 21. These claims define no additional features of the device. They merely define how the device is implanted and in what sequence the device is connected to a fluid pressure source.